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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,589	07/08/2003	Joe S. Wilkins JR.	WRC/8c	8939

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EXAMINER	
ROBERTS, LEZAH	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/615,589	WILKINS, JOE S.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *6-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *A & B*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed March 4, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the reference under other documents beginning with "Medicines & Products" has not been considered due to the failure to enclose a legible copy of the reference.

Claims

Claim Rejections - 35 USC § 112 – Written Description

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are indefinite insofar as the basis for the percent calculation is not set forth, e.g., percent by weight based on the total weight of the composition, percent by volume based on

the volume of the carrier, etc. See Honeywell Intl. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the claimed value is indefinite unless the particular method of measurement is recited.) The percent calculation must either be clearly defined within the specification or set forth within the claim. The claims do not specifically point out if % purity refers to the composition or the initial purity of the starting material, d-limonene, therefore the 98.5% value does not set forth the metes and bounds of the claim.

Claim Rejections - 35 USC § 102 – Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Greathouse et al. (US 3,023,144).

Greathouse et al. teaches biocidal compositions for topical application containing d-limonene. Citrus peel oil has been reported to show activity in vitro against certain Mycobacateria and Staphylococci. The chief constituent of citrus oil is d-limonene (90% of the total composition). D-limonene possesses marked and definite germicidal and fungicidal activity (col. 1, lines 45-71). It also acts as a solvent and penetrant, and when used in combination with its derivatives, surprisingly brings about an enhanced or synergistic fungicidal and bactericidal action (col. 2, lines 38-44). The compositions are formulated into ointments, creams and shampoos (col. 2, lines 50-52). The reference anticipates the claims insofar as to disclose compositions comprising d-limonene for topical use as a fungicide, bactericide and therapeutic composition.

2) Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Chastain et al. (US 5,153,229).

Chastain et al. teaches compositions that contain oxidized d-limonene that possess bactericidal activity against Staphylococcus aureus. The limonene used in the claimed invention is believed to be broad so as to include derivatives such as oxidized d-limonene. The specification does not disclose the compositions were made in a closed environment that would limit or prevent the introduction of oxygen to the composition that would exclude the possibility of auto-oxidation; note that limonene naturally undergoes such auto-oxidation, as taught at col. 2, lines 41 and 42. The limonene can be incorporated in creams, ointments, tinctures, gels, suppositories, paints, sprays, aerosols, toothpastes, solutions,

emulsions, surgical soaps, mouthwashes or antiseptics and can be applied anywhere it is desirable to kill or prevent the growth of bacteria, fungi, or yeasts (col. 4, lines 54-68 and col. 5, lines 1-3). The reference anticipates the instant claims insofar as to disclose composition comprising of d-limonene with the ability to inhibit the growth of bacteria, specifically staphylococcus aureus as well as anticipating using d-limonene in formulations such as creams and ointments.

3) Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Franklin (US 20030180349).

Franklin discloses compositions comprising a single terpene, a terpene mixture, or a liposome-terpene(s) for prevention and treatment of a respiratory infection. One disclosed respiratory problem is sinusitis, which is caused by bacteria such as streptococci and staphylococci (page 1, paragraph 0006). The different terpenes that can be used to make an effective composition in the disclosed invention include limonene (page 8, paragraph 0127). All classifications of natural or synthetic terpenes will work in the invention, anticipating the use of the different isomers of limonene, d-limonene and l-limonene (page 9, paragraph 0133). D-limonene is also referred to in the reference's prior art (page 5, paragraph 0077). The disclosed pharmaceutical compositions include a spray form to deliver the composition to the nasal cavity (page 7, paragraph 0113). The reference anticipates the instant claims insofar as to disclose a nasal spray comprising d-limonene with the ability to inhibit the growth of bacteria, such as streptococci and staphylococci.

Claim Rejections - 35 USC § 103 – Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greathouse et al. in view of Wolff.

The primary reference is as stated supra. The reference differs from the instant claims insofar as to not state the purity of the d-limonene.

Wolff discloses the importance of purity of a medication or food additive. In 1906 the congress of the United States passed the Pure Food and Drug Act, which established more stringent and more desirable criteria of purity of drugs and food additives. The purity of a drug is not only important to determine potency of the drug composition in order to determine dosage, but possible

impurities may cause unwanted side effects when administered (pages 23-24, section 6.1).

It would have been obvious to one of ordinary skill in the art to have used the purest possible d-limonene in the compositions in the primary reference motivated by the desire to know the amount of active ingredient in the compositions, to ensure impurities would not cause unwanted effects and to ensure compliance with FDA regulations as stated in the secondary reference.

Obvious Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16 and 17 of copending Application No. 10615588. Although the conflicting claims are not identical, they are not patentably distinct from each other because the oral cavity (recited in the copending application) and the nasal cavity (recited in the instant claims) are interconnected.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner
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